# Chapter 11 Extension of Patent Term

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Where a regulatory approval shall be obtained in accordance with other laws and regulations for the exploitation of an invention patent involving a pharmaceutical or an agrichemical, or the manufacturing process thereof, if such a regulatory approval is obtained after the publication of the concerned invention patent, the patentee may apply for an extension of the patent term of said invention patent based on the first regulatory approval. This chapter deals with the relevant application requirements and examination matters for the extension of patent term. Act 53. I

## 1. Introduction

The patent system is aimed to encourage, protect and utilize the creations of invention, utility model and design in order to promote industrial development. However, a pharmaceutical or an agrichemical that can be directly applied to the human body, or the manufacturing process thereof, in accordance with the relevant laws and regulations of the central competent authorities in charge of the business, for the purpose of ensuring safety and effectiveness, a regulatory approval must be obtained before the patent can be exploited. It often takes a considerable period of the time from the patent is granted to it is actually sold on the market. Therefore, most of the pharmaceutical or agrichemical inventions have lost part of their patent term when they are approved to the market by the central competent authorities in charge of the business. Under such circumstance, it will reduce the willingness of the industry to develop and invest in the research and development of new drugs, and it is difficult to expect to improve the health and well-being of humans. To solve this problem, the Patent Act establishes a patent term extension system to compensate the period of the invention patent involving a pharmaceutical or an agrichemical, or the manufacturing process thereof cannot be exploited until obtaining a regulatory approval in accordance with the laws.

An invention patent involving a pharmaceutical or an agrichemical, or the manufacturing process thereof, for the purpose of ensuring safety and effectiveness, etc., which must obtain a regulatory approval and fails to be exploited from the date of the patent published, the patentee may apply for an extension of the patent term. The extension term is limited to five years. Act 53. II

Referred to the Act, "a regulatory approval shall be obtained in accordance with other laws and regulations" means in the case of pharmaceuticals, it refers to the provisions of Article 39 of the Pharmaceutical Affairs Law, which stipulates that drugs shall be filed with the central competent health authority for registration and market approval, and no manufacturing or importation of such drugs shall be allowed until a drug permit license is approved and issued, or it refers to the provision of Article 14 of the Prevention of Rare Diseases and Orphan Drug Act, which stipulates that unless otherwise regulated in this Act, orphan drugs shall not be manufactured or imported without the registration and market approval, and drug permits issued, by the central competent authority. In the case of agrichemicals, it refers to the provisions of Article 9 of the Agro-pesticides Management Act, which stipulates that agro-pesticides shall not be manufactured, processed, or imported without having passed the examination of, approval for registration with, and obtained a permit from the central competent authority.

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The pharmaceuticals that can apply for an extension of the patent term are limited to those that can enhance human health and well-being, excluding veterinary drugs.

Reg. 2

In this chapter, the term "central competent authorities in charge of the business" refers to the Ministry of Health and Welfare for pharmaceuticals, or the Ministry of Agriculture for agrichemicals.

In this chapter, applying for an extension of patent term or filing a requesting for a patent term extension is abbreviated as "the application of extension". The Ministry of Health and Welfare is abbreviated as "MOHW", the Ministry of Agriculture is abbreviated as "MOA".

## 2. Requirements of the application of extension

### 2.1 Categories of the invention patent of the application of extension

According to Article 39 of the Pharmaceutical Affairs Law, Article 14 of the Prevention of Rare Diseases and Orphan Drug Act and Article 9 of the Pesticide Management Law, all patentees who have obtained invention patents for pharmaceuticals or agrichemicals, or the manufacturing process thereof shall obtain regulatory approvals issued by the central competent authorities in charge of the business before they can exploit their invention patents. Therefore, the categories of the invention patent eligible for the application of extension are limited to those involving pharmaceuticals or

agrichemicals, or the manufacturing process thereof. Regarding whether an invention patent belongings to pharmaceuticals, in principle, it should refer to the relevant provisions of the Pharmaceutical Affairs Law. For example, pharmaceuticals defined in Article 6 of the Pharmaceutical Affairs Law, include drugs used in diagnosing, curing, alleviating or preventing the diseases of human beings, other drugs which are sufficient to affect the body structure and physiological function of human beings, etc. Invention patents not for pharmaceuticals or agrichemicals, or the manufacturing process thereof are ineligible for the application of extension, such as invention patents involving medical equipment, cosmetics, health foods, packaging of pharmaceuticals or agrichemicals, intermediates or catalysts used during the manufacturing process of pharmaceuticals or agrichemicals, pharmaceutical machinery or devices, chemicals other than pharmaceuticals and agrichemicals and their uses, etc.

A synergist or auxiliary agent that is not an active ingredient per se is ineligible for the application of extension, even if the synergist or auxiliary agent is a subject of an invention patent for a pharmaceutical or an agrichemical, or the manufacturing process thereof.

Utility model patents or design patents, even if they involve pharmaceuticals or agrichemicals, are also ineligible for the application of extension.

### 2.2 Applicants of the application of extension

The person who applies for an extension of patent term (hereinafter referred to as "the applicant") is limited to the patentee. When the patentee exclusively authorizes others to implement, the exclusive licensee may also be the applicant. Act 53. I

If the patent is jointly owned by two or more co-owners, each co-owner can independently apply for an extension unless otherwise the contract between the co-owners has appointed a representative. Act 12. II

### 2.3 The first regulatory approval

#### 2.3.1 The holder of the first regulatory approval

The holder of the first regulatory approval can be the patentee, exclusive or non-exclusive licensee. Act 62. I

If the holder of the first regulatory approval and the patentee are inconsistent in form, the applicant shall submit a document to prove that both

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have the same legal personality or have an exclusive or non-exclusive authorization relationship. Moreover, the authorization is not limited to the authorization registration, but the applicant should submit the certification document of the fact that the authorization has been completed at the time of of the application of extension. If the document of proof is not submitted or the document of proof is still incomplete, the application of extension should be rejected.

If the holder of the first regulatory approval is a sublicensee of a non-exclusive licensee, the applicant must submit documents to prove the following relationship:

(1)the authorization relationship between non-exclusive licensee and sub-licensee; and

(2) non-exclusive licensee has the right to reauthorize others to implement.

### 2.3.2 Determination of the first regulatory approval

Act 53. I

According to the application for the extension of the regulatory approval, it shall be the first one obtained in accordance with the relevant laws and regulations for exploiting the invention patents for a pharmaceutical or an agrichemical, or the manufacturing process thereof. The term "the first regulatory approval" refers to the initial approval obtained for the same active ingredient and the same use. For example, for a drug with the same active ingredient and use, if two or more approvals are obtained successively, the first approval obtained is "the first regulatory approval".

The aforementioned "active ingredient(s)" shall be based on the active ingredient(s) listed in the " Prescription " column of the drug permit license for pharmaceuticals; or the active ingredient(s) listed in the "Type and Content of Active Ingredient" column of the agro-pesticide permit license for agrichemicals. In principle, different approvals for different salts, different esters or different hydrates of the same chemical moiety can be regarded as the first regulatory approval. For example, an invention patent for the application of extension claims "a compound A and its salts", if the applicant successively obtains different approvals for the formate of compound A and bisphosphonate of compound A for the same use, each of the different approvals obtained one after another can be regarded as the first regulatory approval, and the applicant can choose one of the approvals to apply for the extension of the invention patent.

The aforementioned "use(s)" shall be based on the contents listed in the "Indication" column of the drug permit license for pharmaceuticals, or the

contents listed in the "Method of Use and Scope of Use" column of the pesticide permit license.

Drug raw materials or technical grade agro-pesticides are materials used for manufacturing pharmaceuticals or agrichemicals per se, and not for the uses of pharmaceuticals or agrichemicals, therefore, a regulatory approval obtained for the drug raw material or the technical grade agro-pesticide is not considered as "the first regulatory approval" pursuant to the Act.

According to the practice of the central competent authorities in charge of the business, for the same active ingredient, after reviewing and inspection for registration, it is possible to issue multiple approvals based on new uses, new dosage forms, new administration doses or new unit strength etc., by issuing separate licenses or adding changes to the same license. Thus, regarding the determination of the first regulatory approval further explanation is as follows:

(1) The cases where multiple licenses are obtained for different uses of the same active ingredient:

(i) Regarding pharmaceuticals, in principle, each approval obtained with different uses for the same active ingredient can be used as the first regulatory approval for the application of extension. If the registration of the new use is issued by adding change to the same license, for example, where the dosage form, administration dose, and the active ingredient are all the same, then only the use is different, the applicant must specify stated use approval for the application of extension on a request form. In the case where changes are added to the same drug license, it should be noted that, if a new indication is approved besides the originally approved indications, this approval is a different use approval for the same active ingredient, and shall be regarded as the first regulatory approval. For example, the drug permit license with interferon as the active ingredient and with Kaposi's sarcoma as the indication, the change is noted "Indication amendment, to add: treating active chronic hepatitis B effectively", it means the indication of treating active chronic hepatitis B is added other than the indication for Kaposi's sarcoma. Therefore, the approval of changing indication is regarded as the first regulatory approval.

(ii) Regarding agrichemicals, if there are multiple approvals issued because of the expansion of the scope of use (such as adding new crops or new control targets, etc.), and the multiple approvals are based on the same nature of action (for example, all used as fungicides, all used as

insecticides, or all used as herbicides etc.), the earliest approval issued shall be regarded as the first regulatory approval. For example, the approval obtained previously is an active ingredient A used to control *Pieris canidia* in cabbage, and the approval obtained subsequently is the active ingredient A used to control aphids in cabbage (new control target), because the two approvals are all used for pest control based on the same nature of the action, the approval obtained subsequently for the active ingredient A to control aphids in cabbage is not the first regulatory approval. Another example, the approval obtained previously is an active ingredient B used to control powdery mildew in grapes, and the approval obtained subsequently is the active ingredient B used to control powdery mildew in papaya (new applicable crop). Because the two approvals are all used to control powdery mildew based on the same nature of the action, the approval obtained subsequently for the active ingredient B to control powdery mildew in papaya is not the first regulatory approval. For another example, the approval obtained previously is an active ingredient C to control bacterial leaf blight of rice, and the approval obtained subsequently is the active ingredient C to control bacterial streak disease of gramineous crops (new applicable crop and control target), although control targets of the two approvals are different, because the two approvals are all used as fungicides and are still based on the same nature of action, the approval obtained subsequently for the active ingredient C to control bacterial streak disease of gramineous crops is not the first regulatory approval.

(2) The cases where multiple licenses are obtained for the same active ingredient and the same use:

(i) "The first regulatory approval" refers to the initial approval obtained for the same active ingredient and the same use. For the same active ingredient and the same use, the approvals obtained subsequently based on different dosage forms, different administration doses or different unit contents etc. shall be not regarded as the first regulatory approval.

(ii) Among the approvals obtained successively, while the registration of the new use approval is to add changes to the license of the same active ingredient, if it is due to the name of the indication is changed (for example, the MOHW announces that the medicine contains diclofenac, the indications of the eye drops are unified revised as "eye inflammation after cataract surgery"), or the new indication is related to the previous

indication, and result in the changed indication replaces the indication approved originally, in such cases, the approval of the changed indication is not regarded as the first regulatory approval.

### 2.4 Statutory period for the application of extension

Act 53.Ⅳ The application for patent term extension shall be filed to the Specific Patent Agency within three months after obtaining the first regulatory approval; no request for patent term extension shall be filed within six months prior to the expiry of the original patent term.

Since the date of issuance of the drug permit license and the date when the patentee or licensee actually obtains the license may not be the same. Therefore, the date of obtaining the first regulatory approval is based on the date when the patentee or licensee actually obtains the license. Where the application for registration of a drug permit license with a change of use (referring to newly added indication for pharmaceuticals, or the expansion of the scope of use for agrichemicals), and the use is added to the original license after it is approved, the actual date of obtaining the license refers to the actual receipt of the original drug permit on which a change use is noted.

If the applicant is unable to provide proof of the actual date of obtaining the license, the date of obtaining the first regulatory approval shall be based on the date of issuance contained in the license; if the application for registration of a change of use, the date of approval of the change item contained in the license shall be quasi.

### 2.5 Times of the application of extension

The legislative purpose of the patent term extension system is to compensate for the period during which the invention patents involving pharmaceuticals, agrichemicals, or the manufacturing process thereof cannot be exploited unless they obtain the regulatory approvals via statutory examination. Therefore, the patentee may apply for one and only one extension of the patent term for one invention patent. If an invention patent has been granted for extension of the patent term, said invention patent shall not be granted again to render another patent term extension. For example, the extent of the protection conferred by an invention patent includes an active ingredient A and its use as a bactericide and insecticide, once the invention patent has been applied and granted for a patent term extension in accordance with the pesticide permit license for bactericide, it is no longer

for further application of term extension in accordance with the pesticide permit license for insecticide. If both of the bactericide license and pesticide permit license are used to apply for extension for the same patent case at the same time, the patentee can choose only one of the licenses to apply for term extension.

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In addition, the patentee can only apply for one and only one term extension based on the first regulatory approval. If the first regulatory approval has been applied for extension, the patentee shall not use the same approval to apply for extension of the patent term for the same or other patents again. Therefore, after obtaining the first regulatory approval, if the approval can correspond to the claims of multiple invention patents at the same time, the patentee can only choose one of the invention patents to apply for term extension.

### 3. Filing an application of extension

Reg 3. Ⅱ

Those who apply for a patent term extension shall submit a request form to the Specific Patent Agency. A copy of the regulatory approval obtained in accordance with the law, and the domestic and/or foreign document(s) of proof regarding for application the regulatory approval shall be attached with the request form.

#### 3.1 Matters stated in the request form

Reg.3. Ⅰ

A request form for a patent term extension must state the number of patent certificate, the title of invention, the name(s) of patentee, the reason for the extension, the term of extension and the date of obtaining the first regulatory approval, etc. The following is an explanation of the relevant matters that should be recorded in the request form.

##### 3.1.1 The existence of invention patent right

The request form shall state the number of the patent certificate, the publication date of the patent, the expiry date of the patent right and the existence of invention patent right (e.g. patent annuity payment record).

##### 3.1.2 Descriptions regarding the matters of the first regulatory approval

The applicant shall record in detail the history and period of the inability to exploit the invention in order to obtain the first regulatory

approval, which is the main basis for the application for extension. The descriptions regarding the matters of the first regulatory approval shall include the following items:

(1) The law on which the regulatory approval is based

In accordance with Article 39 of the Pharmaceutical Affairs Law, or Article 14 of the Prevention of Rare Diseases and Orphan Drug Act, pharmaceuticals shall obtain drug permit licenses before their patent rights can be exploited. In accordance with Article 9 of the Pesticide Management Law, agrichemicals shall obtain pesticide permit licenses before their patent rights can be exploited.

(2) The specific matters recorded in the first regulatory approval.

The reason of the application of extension shall state the content of the first regulatory approval, including the active ingredient(s) and its use of the license. For pharmaceuticals, it usually reproduces the active ingredient(s) contained in the " PRESCRIPTION " column and the content contained in the " INDICATION " column of the drug permit license; for agrichemicals, it usually reprints the active ingredient(s) and the content contained in the " METHOD OF USE AND SCOPE OF USE " column of the pesticide permit license.

(3) Correlation between the active ingredient(s) and use(s) thereof of the first regulatory approval and the Claim(s) of the patent.

Where the application of extension is for invention patent involving pharmaceuticals or agrichemicals, or the manufacturing process thereof, the Claim(s) must cover the active ingredient(s) and use(s) recorded in the first regulatory approval. Therefore, the request form must state the correlation between the active ingredient(s) and the use(s) thereof, recorded in the first regulatory approval, and the Claim(s) of the patent. It should be noted that if the manifestation of the active ingredient(s) and use(s) recorded in the first regulatory approval is inconsistent with the contents of the concerned claims, the applicant must explain the relationship between the two in detail, if there is a record of the relationship between the two in the patent specification, the recorded part should be specified. For example, in the case when the claim is a compound represented by a chemical formula or chemical name, while the active ingredient listed in the regulatory approval is expressed by the name, scientific name, or popular name recorded in the pharmacopoeia, in addition to providing the basis for the pharmacopoeia records, the applicant must clearly state the chemical formula or chemical name of

active ingredient and its relationship with the claimed compound, and if the patent specification has described the claimed compound represented by a chemical formula or chemical name is the same as the name, scientific name, or popular name recorded in the pharmacopoeia, the applicant must indicate the part of description in the patent specification. For another example, the medical use described in the claim is defined by the pharmacological mechanism, while the indication recorded in the drug permit license is the name of a specific disease, the applicant must explain the relationship between the pharmacological mechanism and the specific disease, if there is a record of the relationship between the two in the patent specification, the record part shall be indicated.

### 3.1.3 The history and period in which the invention cannot be exploited in order to obtain a regulatory approval

The reason for the application of extension must state the history of which the invention cannot be exploited to obtain a regulatory approval, that is, the main facts and the periods related to obtaining a regulatory approval.

#### 3.1.3.1 The history and period in which the invention cannot be exploited in order to obtain a regulatory approval

Regarding the history of which the invention cannot be exploited in order to obtain a regulatory approval, for pharmaceuticals, the domestic and/or foreign clinical trial plans conducted for obtaining a drug permit license issued from the WHOH, and the date of commencement and expiration thereof, and the reviewing process and related periods of filing a domestic application for inspection and registration of drug shall be stated; for agrichemicals, the domestic and/or foreign field test plans conducted for obtaining a pesticide permit license issued from the MOA, and the date of commencement and expiration thereof, and the reviewing process and related periods of filing a domestic pesticide registration shall be stated. The description of each period mentioned above is as follows.

##### 3.1.3.1.1 The periods of domestic and/or foreign clinical trials

(1)The periods of domestic clinical trials

The commencement date of the domestic clinical trial period of the pharmaceutical refers to the date of an official consent letter issued by the WHOH to approve the applicant to conduct the domestic clinical trial

(including bridging trial). The expiration date of a domestic clinical trial period of the pharmaceutical refers to the date of an official consent letter for inspection of reports issued by the MOHW while the reports of the domestic clinical trial (including the bridging trial) are consented for inspection. The aforementioned bridging trial shall be conducted via the evaluation of the MOHW. If different clinical trials are conducted with the same active ingredient, the date on which the MOHW consent to conduct each trial, and date of the consent letter of each clinical trial report for inspection should be indicated as the commencement and expiration date of respective trial period.

(2) The periods of foreign clinical trials

Those who apply for extension based on foreign clinical trial periods shall state the main items of the foreign clinical trial plans, such as the name of the trial plan, plan number, trial drugs, trial phases, etc., and state the study initiation date and study completion date, as defined in the clinical trial report complied with ICH (International conference on harmonization of technical requirements for registration of pharmaceuticals for human use), to be the commencement and expiration date of the foreign clinical trial.

#### 3.1.3.1.2 The examination period of inspection and registration of domestic application for regulatory approval of drug

Regarding the examination period for domestic application for regulatory approval of drug, the commencement date shall be the date of application for inspection and registration to the MOHW (subject to the date of receipt by the MOHW) , and the expiration date shall be the date of the actual receipt of the permit license (usually the date recorded in the label sticker form of drug use instruction).

#### 3.1.3.1.3 The periods of domestic and/or foreign field tests

The period of domestic field tests of agrichemicals, in principle, the start date refers to the date when the agency (or institutions), schools, legal persons or organizations recognized by the MOA start the field tests of pesticides; the completion date refers to the date when the field tests are completed, that is, the start and completion dates are recorded in the field test report.

As for the examination of pesticide registration by the MOA, the written

examination materials include foreign field test data. Therefore, those applying for extension based on the foreign field tests should state the key points of the foreign field test plan, such as the test plan name, plan number, pesticide name, pesticide application scope, etc., and record the dates on which the field test starts to conduct and completes as the commencement and expiration dates of the foreign field test period.

#### 3.1.3.1.4 The examination period for domestic application for regulatory approval of pesticide

Regarding the examination period for domestic application for regulatory approval of pesticide, the commencement date shall be the date on which the applicant submits the relevant registration materials and received by the MOA for the pesticide registration; the expiration date shall be the date of issuance recorded on the pesticide permit license.

### 3.1.3.2 Calculation of the period in which the invention cannot be exploited in order to obtain a regulatory approval

The period during which the invention cannot be exploited for the purpose of obtaining a regulatory approval is calculated according to each period of the domestic and/or foreign trial or test, as stated in this chapter section 3.1.3 " The history and period in which the invention cannot be exploited in order to obtain a regulatory approval " (if the commencement date of the domestic and/or foreign trial or test is before the publication date of a patent, it shall be counted from the publication date; and if the commencement date of the domestic and/or foreign trial or test is after the publication of a patent, it shall be counted from the commencement date of the trial or test), and the examination period for application of domestic regulatory approval (it is calculated to the day before the actual date of receipt of the license). After summing them up, it is calculated (in "day") by deducting the overlapping periods of domestic and/or foreign tests, and the overlapping periods between domestic and/or foreign tests and examination period for regulatory approval. By calculation, even if the calculated period exceeds five years, it shall still be recorded based on the calculated actual non-exploitation period.

Reg. 8

Reg. 4.Ⅲ

Reg. 6.Ⅲ

### 3.1.4 Record of the application of extension period

If the period for which the invention cannot be exploited in order to

obtain a regulatory approval is less than five years, the period of the application of extension shall be in "day" as the unit, and recorded as "The period of the application for patent term extension is ○ days"; and if the period of the application for patent term extension exceeds five years, the period shall be limited to five years and recorded as "The period of the application for patent term extension is five years". Reg. 3. II

### 3.2 Documents to be attached

Those who apply for an extension of patent right period shall attach a copy of the regulatory approval obtained in accordance with the law and the domestic and/or foreign certification document(s) for the application of the regulatory approval, which are described below. Reg. 5. I

#### 3.2.1 Pharmaceuticals or manufacturing process thereof

Where a patent involving a pharmaceutical or manufacturing process thereof applies for a patent term extension, in addition to the copy of the drug permit license, the following documents shall be attached：

(1) Document(s) and checklist(s) for the domestic clinical trials period (including bridge study period), the foreign clinical trials period and the commencement and expiration dates thereof. The list shall list the plan title, plan number, start and completion date of each clinical trial plan. (See the appendix for an example of clinical trial lists of pharmaceuticals)

(2) Certification documents of the examination period of domestic application of the regulatory approval for pharmaceuticals and the commencement and expiration dates thereof.

The certification documents of the above-mentioned domestic clinical trial(s) (including bridge study) regarding the commencement and expiration date thereof refer to the consent letter to conduct the trial issued by the WHOH, and the subsequent consent letter of the clinical trial report (including bridge study reports) for reference. Those who apply for an extension based on the bridge study shall additionally submit the relevant documents of the application for the bridge study assessment and its assessment results to the MOHW.

The certification documents regarding the commencement and expiration date of the foreign clinical trial period shall be the documents issued by the trial unit or institution, etc. that conducts the clinical trial abroad, such as providing the copy of the title page of the clinical study

report in which the study title, the plan number, the trial drug, the development phase of study, trial unit and initiation date and study completion date of the plan, etc. are recorded.

Reg. 7. I

The certification document regarding the commencement date of the examination period for domestic application for the regulatory approval shall be an official document sufficient to prove the date of application for regulatory approval, such as a notification letter containing the date of receipt by the MOHW; as for the expiration date, the certification document is usually a copy of label sticker form of drug use instruction.

Since the central competent authority in charge of the business for pharmaceuticals has incorporated the review of domestic and foreign clinical trials required for the issuance of a drug permit license into the "Data Exclusivity Period and Domestic and Foreign Clinical Trial Data Table," and reviews and confirms the clinical trial data submitted by the applicant—noting determined results on said table in case of amendments and stamping it with the authority's seal on the seams for confirmation—if an applicant submits this table as a certification document for the clinical trial period, the trials confirmed by the authority as necessary for the license may directly use said table as the basis for determination.

### 3.2.2 Agrichemicals or the manufacturing process thereof

Where a patent involving an agrichemical or manufacturing process thereof applies for a patent term extension, in addition to the copy of the pesticide license, the following documents shall be attached：

(1) Document(s) and checklist(s) for the domestic and/or foreign field tests period and the commencement and expiration dates thereof. The checklist shall list the plan title, plan number, start and completion date of each field test. (See the appendix for an example of field tests list of agrichemical)

(2) Certification documents of the examination period of domestic application of the regulatory approval for agrichemicals and the commencement and expiration dates thereof.

The certification documents of the above-mentioned domestic and/or foreign field tests and the commencement and expiration dates thereof shall be the documents issued by the test unit or institution, etc., that conduct the field tests, such as providing the copy of the title page of the test report in which the test title, the test number, the test pesticide, the test unit and start date and completion date, etc., are recorded.

The certification document regarding the commencement date of the

examination period for domestic application for the regulatory approval of agrichemicals shall be official documents sufficient to prove the date that the applicant has completed the receipt of agro-pesticide registration by the MOA, such as a copy of the application for permit registration with the date of receipt. As the certification document of the expiration date, it is usually a copy of the pesticide permit with the date of issuance.

### 3.3 Example of the request form（Take pharmaceutical as an example）

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1. Status of invention patent

   | | |
   |---|---|
   | Filing date | (mm/dd/yyyy) |
   | Publication date | (mm/dd/yyyy) |
   | Expiry date of the patent right period | (mm/dd/yyyy) |
   | Effective date of patent annual fee | (mm/dd/yyyy) |

2. Description of the matters of the regulatory approval
   (1) The law on which the regulatory approval obtained is based.
   According to Article 39 of the Pharmaceutical Affairs Law, and a drug permit licenses must be obtained before the patent right can be exploited.
   (2) Number of Drug permit license: ○○○
   (3) The relationship between the holder of the regulatory approval and the patentee: the same person.
   (4) The specific approval items recorded in the regulatory approval
   Active ingredient: ○○○
   Indication: ○○○
   (5) The correlation between the active ingredient(s) (or the active ingredient(s) and use thereof) of the regulatory approval and the Claims of the patent.
   The active ingredient(s) of the regulatory approval obtained in accordance with the laws falls within the scope of claim 1 of the invention patent "A compound of formula (I), wherein $R_1$ is a hydrogen atom".
3. The reasons of the application of extension

(1) The facts of which the invention patent term cannot be exploited for obtaining a regulatory approval: (omitted)

(2) The history of which the invention patent term cannot be exploited for obtaining a regulatory approval:

A. Periods of the domestic and/or foreign clinical trials

Start date of the bridge study: (mm/dd/yyyy)

Completion date of the bridge study: (mm/dd/yyyy)

Start date of the foreign clinical trial: (mm/dd/yyyy)

Completion date of the foreign clinical trial: (mm/dd/yyyy)

B. Examination period of the inspection and registration

Date of applying for the first regulatory approval: (mm/dd/yyyy)

Date of obtaining the first regulatory approval: (mm/dd/yyyy)

(3) The period in which the invention cannot be exploited for obtaining a regulatory approval: total ○ days.

4. The period for the application of extension: The period for the application of extension is ○ days.

5. The date of obtaining the first regulatory approval: (mm/dd/yyyy)

6. Materials attached

A. A copy of patent gazette, invention patent publication No. ○○○ and date (mm/dd/yyyy)

B. A copy of the license No. ○○○

C. A copy of the label sticker form of drug use instruction

D. One copy of the certificated document(s) regarding the period of the bridge study and the commencement and expiration dates thereof

E. One copy of the certificated document(s) regarding the application for assessment of the bridge study and the result of the assessment

F. One copy of the certificated document(s) regarding the commencement and expiration dates thereof of the foreign clinical trial period

G. Two copies of the checklist of the domestic and/or foreign clinical trials (the clinical trials materials submitted for inspection and registration shall be indicated, for example, “Page ○ of the Disc ○ for Review" or "Page ○ of the book ○ Submitted for Review")

### 3.4 Publication of the application of extension

Reg. 3.Ⅲ

When accepting an application for extension, the contents of the request form for the application shall be publish for the public to know the status of

the application of extension of the patent right period.

**4. Examination of the application of extension**

For the examination of the application of extension, in addition to examining whether the applicant and the invention patent meet the requirements for the application of extension, it must also confirm and determine whether or not, the relevant periods are adopted based on the contents stated in the reasons for applying the extension with reference to the attached certificated documents. Since the domestic and/or foreign clinical trials (for pharmaceuticals) or the field tests (for agrichemicals) adopted shall be limited to those confirmed by the central competent authority in charge of the business for the issuance of regulatory approval, while examining, the checklist attacted by the applicant of listing various trials or tests shall be sent to the central competent authority in charge of the business for confirmation, and then continue the examination after the central competent authority in charge of the business replies the results. If an applicant submits the "Data Exclusivity Period and Domestic and Foreign Clinical Trial Data Table" bearing the stamp on the seams from the central competent authority in charge of the business as certification documents for the periods of domestic and foreign clinical trials, it is not necessary to request confirmation from the central competent authority in charge of the business, and examination may be conducted directly based on said data table. However, if the document is not the aforementioned data table reviewed and confirmed by the MOHW, or if there is any doubt regarding the content reviewed and determined according to said data table, a letter may be sent to the MOHW for confirmation. The following only explains the relevant matters of the examination, and the adoption and calculation of the granted extension period.

Reg. 4. Ⅱ
Reg. 6. Ⅱ

**4.1 Determination of the first regulatory approval**

To determine whether a regulatory approval for the application of extension is the first regulatory approval, the active ingredient(s) and use identified in the regulatory approval shall be checked first, such as using the license query system on the website of the central competent authority in charge of the business for inquiries, if necessary, the Specific Patent Agency can request the central competent authority in charge of the business to assist in confirmation.

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If the regulatory approval for the application of extension is not the first regulatory approval, or the same regulatory approval has been used to extend the patent term of other invention patents, the patent term extension shall not be granted.

### 4.2 To deal with the holder of the first regulatory approval is not the applicant

If the applicant is not the holder of the first regulatory approval, the applicant and the holder of the first regulatory approval shall have an authorization relationship. If the holder of the first regulatory approval is not the applicant, the applicant shall be notified to submit the certification documents of the fact that the authorization has been completed at the time of filing the extension request. If the certification documents have not been submitted by the deadline or the certification documents are still incomplete, the extension request shall be rejected.

### 4.3 Determination of the correlation between patent Claims and the First Regulatory Approval

Examination of the application of extension, it must confirm that the active ingredient(s) and use(s) recorded in the first regulatory approval need to be covered by the Claim(s) of the patent application in the case. In the case of invention patent regarding substance, the active ingredient(s) recorded in the first regulatory approval must be covered by the substance claims; in the case of invention patent regarding use, the active ingredient(s) and use(s) recorded in the first regulatory approval must be covered by the use claims; in the case of invention patent regarding manufacturing process of the substance, the active ingredient(s) recorded in the first regulatory approval need to be covered by the substance obtained according to the process claims.

Regarding the determination of the correlation between the active ingredient(s) and use(s) recorded in the First Regulatory Approval and the Claims of the patent of the application of extension, examples are as follows:

(1) For invention patent regarding substance, at least one of the claims must cover the active ingredient(s) recorded in the regulatory approval.

**Example 1**

<u>The patent for the application of extension:</u>

Claim 1: A compound A.

Claim 2: A compound A according to claim 1, it is a compound a. (compound a is covered by the scope of compound A)

The first regulatory approval:

PRESCRIPTION: besylate of compound a

INDICATION: analgesia

[Remarks]

The active ingredient listed in the PRESCRIPTION column of the first regulatory approval is the besylate of compound a. Because the salt of compound A is not stated in claim 1 and claim 2, the "besylate of compound a" in the regulatory approval cannot be covered by the scope of claims 1 and claim 2.

**Example 2**

The patent for the application of extension:

Claim 1: A compound B and its salt.

The first regulatory approval:

PRESCRIPTION: Compound b (compound b is covered in the scope of compound B)

INDICATION: Combination with other anticancer agents to treat breast cancer

[Remarks]

The active ingredient listed in the PRESCRIPTION column of the regulatory approval is compound b. Although the INDICATION column of the first regulatory approval states that it must be used in combination with other anticancer agents, however, the PRESCRIPTION column only records compound b as a single active ingredient, so compound b should be used to compare with the compound B of claim 1. It is determined that compound b is covered by the scope of compound B of claim 1, and the active ingredient contained in the first regulatory approval shall be considered as to be covered by the scope of claim 1.

**Example 3**

The patent for the application of extension:

Claim 1: A compound A and its isomers.

Claim 2: A compound A and its isomers according to claim 1, it is a L-form compound a.

The first regulatory approval:

PRESCRIPTION: L-form isomer of compound a

INDICATION: analgesia

[Remarks]

The active ingredient listed in the prescription column of the first regulatory approval is L-form of compound a. It is determined that the L-form of compound a is covered by the scope of claim 1 and 2, and the active ingredients recorded in the first regulatory approval shall be considered as to be covered by the scope of claim 1 and claim 2.

**Example 4**

The patent for the application of extension:

Claim 1: A compound A and its pharmaceutically acceptable salts.

Claim 2: A compound A and its pharmaceutically acceptable salts according to claim 1, said compound A is a compound a.

The first regulatory approval:

PRESCRIPTION: Formate of compound a

INDICATION: analgesia

[Remarks]

The active ingredient listed in the PRESCRIPTION column of the first regulatory approval is formate of compound a, which is a pharmaceutically acceptable salt, so the formate of compound a is covered by the scope of claim 1 and claim 2, and the active ingredients listed in the first regulatory approval shall be considered as to be covered by the scope of claim 1 and claim 2.

**Example 5**

The patent for the application of extension:

Claim 1: A compound C.

Claim 2: A pharmaceutical composition comprising a compound C.

The first regulatory approval:

PRESCRIPTION: Trihydrate of compound c (compound c is covered in the scope of compound C)

INDICATION: Antibiotics

[Remarks]

The active ingredient recorded in the PRESCRIPTION column of the first regulatory approval is the trihydrate of compound c, but claim1 and claim 2 only claim compound C, not hydrate of compound C, so the trihydrate of compound c recorded in the regulatory approval cannot be covered by the scope of claim 1 and claim 2.

**Example 6.**

The patent for the application of extension:

Claim 1: A β-form crystal of ivabradine hydrochloride.

Claim 2: A pharmaceutical composition comprising a β-form crystal of ivabradine hydrochloride.

The first regulatory approval:

PRESCRIPTION: Ivabradine hydrochloride

INDICATION: Treat chronic heart failure

[Remarks]

The active ingredient recorded in the PRESCRIPTION column of the first regulatory approval is “ivabradine hydrochloride”, not β-form crystal of ivabradine hydrochloride, and cannot be covered by the scope of claim 1 and claim 2.

**Example 7**

The patent for the application of extension:

Claim 1: Amisulpride. (optical heterogeneity is undefined)

The first regulatory approval:

PRESCRIPTION: S(-) amisulpride

INDICATION: Anti-anxiety

[Remarks]

The amisulpride of claim 1 does not define optical heterogeneity and can be regarded as a racemic compound, so the S(-) amisulpride recorded in the first regulatory approval cannot be covered by the scope of claim 1.

**Example 8**

The patent for the application of extension:

Claim 1: An anticancer composition comprising a compound A.

Claim 2: An anticancer composition according to claim 1, also comprising a compound B.

The first regulatory approval:

PRESCRIPTION: Compound a

Compound b

INDICATION: Treat bone cancer

[Remarks]

The active ingredient recorded in the PRESCRIPTION column of the first regulatory approval is a combination of compound a and compound b,

the INDICATION is for treatment of bone cancer. Since the anticancer composition of claim 1 is open-ended defined, it is determined that the active ingredient and use recorded in the first regulatory approval are covered by the scope of claim 1 and claim 2.

**Example 9**

The patent for the application of extension:

Claim 1: An anticancer composition consisting of a compound A and a compound B.

The first regulatory approval:

PRESCRIPTION: Compound a
Compound b

INDICATION: Treat bone cancer

[Remarks]

The active ingredient recorded in the PRESCRIPTION column of the first regulatory approval is compound a and compound b, and the INDICATION is for treatment of bone cancer, it is determined that the active ingredients and use recorded in the first regulatory approval are covered by the scope of claim 1.

**Example 10**

The patent for the application of extension:

Claim 1: An anticancer composition consisting of compound A and compound B.

The first regulatory approval:

PRESCRIPTION: Compound a
Compound b
Compound c

INDICATION: Treat bone cancer

[Remarks]

The anti-cancer composition of claim 1 is only composed of compound A and B (enclosed form), so the combination of compound a, compound b, and compound c recorded in the first regulatory approval cannot be regarded as to be covered in the scope of claim 1.

(2) For an invention patent with use claims, the content of at least one of use claims must cover the use of the active ingredient(s) recorded in the first regulatory approval. If the form is different, for example, the medical use described in the claim is defined by a pharmacology mechanism, and

the indication recorded in the first regulatory approval is the name of a specific disease, the applicant must explain the relationship between the pharmacological mechanism and the specific disease. If there is a description of the relationship between the two in the patent specification, the part of description shall be indicated.

**Example 1**

The patent for the application of extension:

Claim 1: Use of compound D for manufacturing an antivirus composition.

Claim 2: Use according to claim 1, wherein the compound D is compound d.

Claim 3: Use according to claim 1, wherein the antivirus composition is an anti-HIV agent.

The first regulatory approval:

PRESCRIPTION: Compound d (d is covered in the scope of compound D)

INDICATION: Anti-HIV.

[Remarks]

The active ingredient Compound d recorded in the PRESCRIPTION column of the first regulatory approval is covered in the scope of the compound D, and the use for Anti-HIV is specific concept of antivirus, it is determined that the active ingredient Compound d and use for Anti-HIV recorded in the first regulatory approval are covered in the scope of claim 1 to claim 3.

**Example 2**

The patent for the application of extension:

Claim 1: Use of compound E for manufacturing an anti-tumor drug.

Claim 2: Use according to claim 1, wherein the compound E is compound e.

The first regulatory approval:

PRESCRIPTION: Compound e (e is covered in the scope of compound E)

INDICATION: Treatment of urinary incontinence

[Remarks]

The active ingredient Compound e recorded in the PRESCRIPTION column of the first regulatory approval is covered in the scope of compound E, while the indication recorded for the treatment of urinary

incontinence is different from the use of anti-tumor claimed in claim1 and claim 2, it is determined that the use of the active ingredient Compound e of the first regulatory approval for the treatment of urinary incontinence is not covered in the scope of claim 1 and claim 2.

(3) For an invention patent with manufacturing process claims, the manufactured end products of at least one of process claims must cover the active ingredient recorded in the first regulatory approval.(The regulatory approval does not record of manufacturing process). If the active ingredient recorded in the regulatory approval cannot be directly expressed by the claim, or the way of expression is inconsistent with the content of the claim, the applicant must explain the relationship between the two in detail, if there is a description of the relationship between the two in the patent specification or the claim, the part of the description should be indicated.

**Example 1.**

The patent for the application of extension:

Claim 1: A manufacturing process of compound A.

The first regulatory approval:

PRESCRIPTION: Compound a (a is covered in the scope of compound A)

INDICATION: analgesia

[Remarks]

Since the first regulatory approval does not record the manufacturing process of Compound a, as long as it is determined that the active ingredient Compound a recorded in the first regulatory approval is covered by the scope of compound A, it can be considered that there is a correlation between the first regulatory approval and claim 1.

### 4.4 Examination and calculation for granting the period of extension

Regarding the examination of the granted period of extension, if there are some circumstances such as the period which the extension is applied for cannot be adopted due to incomplete certificated documents, the calculation of the period for the application of extension is incorrect, or the period of inaction attributable to the applicant is unable to be deducted, etc., the applicant shall be notified to submit a reply or supplement materials within a time limit. If the reply is not made by the deadline, or the submitted reply or supplement materials still cannot overcome the above-mentioned

circumstances, the extension period shall be determined based on the existing materials. The following illustrates the allowed periods of extension for pharmaceuticals and agrichemicals respectively.

### 4.4.1 Invention patent for pharmaceutical and manufacturing process thereof

Reg. 4. Ⅰ

Invention patent for a pharmaceutical or manufacturing process thereof, the period of granting an extension of the patent right includes:

(1) the period of domestic and/or foreign clinical trials (including Bridge study) conducted for obtaining a drug permit license issued by the MOHW; and

(2) the examination period for application of domestic regulatory approval.

Reg. 4. Ⅱ

Aforementioned "domestic and/or foreign clinical trials conducted for obtaining a drug permit license issued by the MOHW " shall be limited to those sent by the Specific Patent Agency to the MOHW and confirmed by the latter to be necessary for issuance of a drug permit license.

Since the periods of domestic clinical trials (including Bridge Study) conducted for obtaining a drug permit license issued by the MOHW are based on obtaining the consent of the MOHW, and the subsequent consent to the clinical trial report for inspection is an essential part, the administrative operation period of the application for assessment of bridge study to the MOHW shall not be included.

Reg. 4. Ⅲ

The aforementioned periods shall still be deducted for the following periods:

(1) the period of inaction attributable to the applicant;

(2) the overlapping period of domestic and foreign clinical trials (including bridge study); and

(3) the period of overlap between domestic and foreign clinical trials (including bridge study) and examination period for regulatory approval.

For the determination of the aforementioned period of inaction attributable to the applicant, please refer to 4.4.3 "Period of inaction attributable to the applicant" in this chapter.

### 4.4.2 Invention patent for agrichemical and manufacturing process thereof

Invention patent for an agrichemical and manufacturing process thereof, the period of granting an extension of the patent right includes: Reg. 6. Ⅰ

(1) the period of domestic and/or foreign field tests conducted for obtaining an agrichemical approval issued by the MOA; and

(2) the examination period for domestic regulatory approval.

Aforementioned "domestic and/or foreign field tests" conducted for obtaining an agrichemical approval issued by the MOA shall be limited to those sent by the Specific Patent Agency to the MOA and confirmed by the latter to be necessary for issuance of an agrichemical approval. Reg. 6. Ⅱ

The aforementioned periods shall still be deducted for the following periods: Reg. 6.Ⅲ

(1) the period of inaction attributable to the applicant;

(2) the overlapping period of domestic and foreign field tests; and

(3) the period of overlap between domestic and foreign field tests and examination period for regulatory approval.

For the determination of the aforementioned period of inaction attributable to the applicant, please refer to 4.4.3 "Period of inaction attributable to the applicant" in this chapter.

### 4.4.3 Period of inaction attributable to the applicant

The so-called "period of inaction attributable to the applicant" refers to the period during which the applicant has been negligent in doing its due diligence, resulting in interruption or delay in obtaining the regulatory approval. In the process of obtaining the approval, the circumstances that can be attributed to the applicant's inaction are illustrated below.

(1) For application of drug inspection registration or pesticide registration, the documents and fees that should be provided have been stipulated. If there are incomplete documents, failure to pay the fees, or the documents do not meet the criteria for obtaining a regulatory approval during the review by the MOHW, and a supplement or payment is required, thus resulting in a delay in obtaining a regulatory approval, in principle, it shall be a period of inaction attributable to the applicant.

(2) For drug inspection and registration, after the examination is passed, the MOHW will notify the applicant to obtain the certificate. Therefore, the date of delivery of the notification letter of the certificate shall be regarded

as the date when the MOHW completed the examination of the regulatory approval, so the period counted from one day after the date of delivery of the notification letter to one day before the actual date of obtaining the certificate by the applicant shall be a period of inaction attributable to the applicant.

(3) The pesticide registration shall be published according to the law after examination and approval by the MOA. Since the date of the publication, the pesticide registration applicant has the qualification to apply for the issuance of a pesticide permit license, thus the period from the publication date of the approval of the pesticide "methods of use and its scope" to the date before the issuance date of the pesticide permit license shall be a period of inaction attributable to the applicant.

The aforementioned period of inaction (1), (2) and (3) attributable to the applicant shall be deducted when calculating the granted extension period. As for the calculation basis of the replenishment period, the applicant can be notified to provide relevant information about the history of application for the license (for example, the history record obtained from the "Application Case Status Inquiry" system on the website of the central competent authority for the purpose of business), but examiner can also conduct verification, or write to the central competent authority for the purpose of business to assist in providing information related to the examination process inquired by its information system.

**4.5 Notes of Examination**

(1) Obtaining a drug permit license for a specific indication in the form of a specific compound's prodrug (for example, a specific ester of the specific compound), even if the same specific compound has previously obtained a drug permit license based on the same indication, it must still be considered as the first regulatory approval, but the prodrug form should be covered by the scope of the patent Claim under which the extension is applied.

(2) If the patentee or licensee obtains multiple licenses for the same active ingredient and the same use on the same day (for example, multiple licenses are issued on the same day for the same active ingredient and the same use, only the dosage is different), due to the patentee's filing the extension request based on the first regulatory approval is limited to one time, and the first regulatory approval can only be used to extend patent term for once, so the applicant who applies for the term extension can

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only choose one of the regulatory approvals to apply. If at the time of application for extension, the applicant submits multiple regulatory approvals with the same active ingredients and the same use issued on the same day, the applicant shall be notified to select one of them to apply for extension within one month. If no one approval is selected within the expiration date of notification, the extension request shall be processed in accordance with Article 17 of this Act.

(3) If the patentee or the exclusive licensee is based on two (or more than two) first regulatory approvals issued on the same day with the same active ingredient and the same use, and files the extension requests for two (or more than two) different invention patents, because the first regulatory approval can only be used to apply the patent term extension once, the patentee should be notified to select one of the regulatory approvals to apply for the extension of the concerned patent within one month. If no selection is made after notification, the application for extension shall be rejected. For example, the patentee applies for patent term extension of the patent A with the regulatory approval A, and for patent term extension of the patent B with the regulatory approval B, after examination, if the regulatory approvals A and B are issued on the same day and determined to be with the same active ingredient and the same use (only the dosage is different), the patentee shall be notified to choose patent case A (with regulatory approval A) or patent case B (with regulatory approval B) for the application of extension within one month. If no selection is made after the notification, the application of extension of patent A and patent B shall be rejected.

(4) The premise of the application of extension is relied on the patent right must be valid, however, when the application of extension is approved, it is also necessary that the patent right must still exist; otherwise, there is no benefit in granting the extension. Therefore, for an accepted extension application, at the time of examining, if the patent has been extinguished or is determined to be revoked finally and bindingly, or the claims, corresponding to the active ingredient(s) and use indicated in the first regulatory approval on which the application of extension is based, have been deleted or revoked finally and bindingly, since the subject matter of the application of extension no longer exists, the application for extension shall be rejected. However, if the application of extension is pending when the original patent right period expires, the examination shall still be continued.

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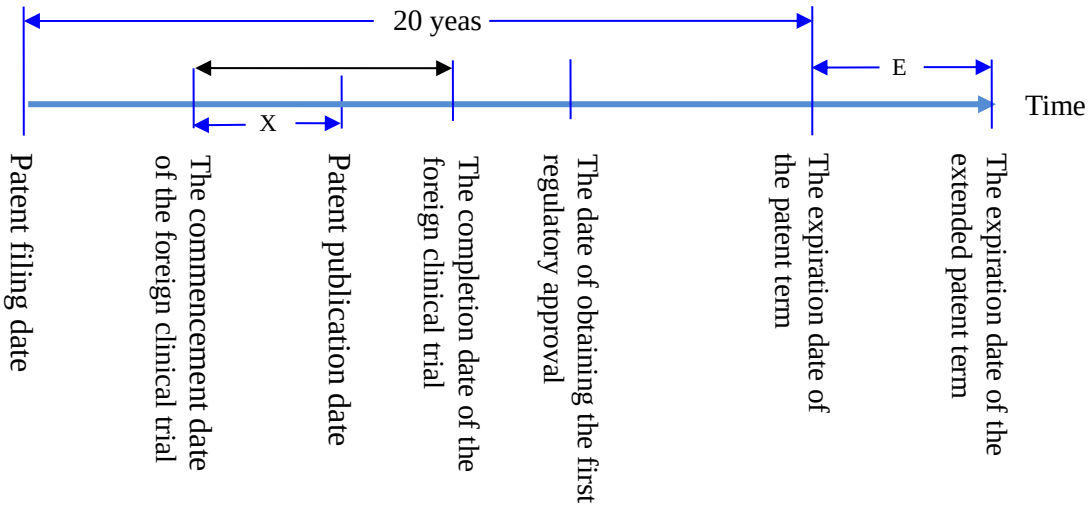
(5) In principle, domestic clinical trials for academic research are not regarded as the period of domestic clinical trials, but with the consent of the MOHW, the domestic clinical trials can be converted into domestic clinical trials for inspection and registration, and may be counted for the period of domestic clinical trials. In this event, the commencement date shall be the date when the domestic clinical trials for academic research start to be conducted, not the switchover date.

### 4.6 Cases

The following examples illustrate the calculation method for the extension of the patent right period.

**Case 1.**

The starting date of foreign clinical trials is before the publication date of a patent, and the starting date shall be counted from the publication date.

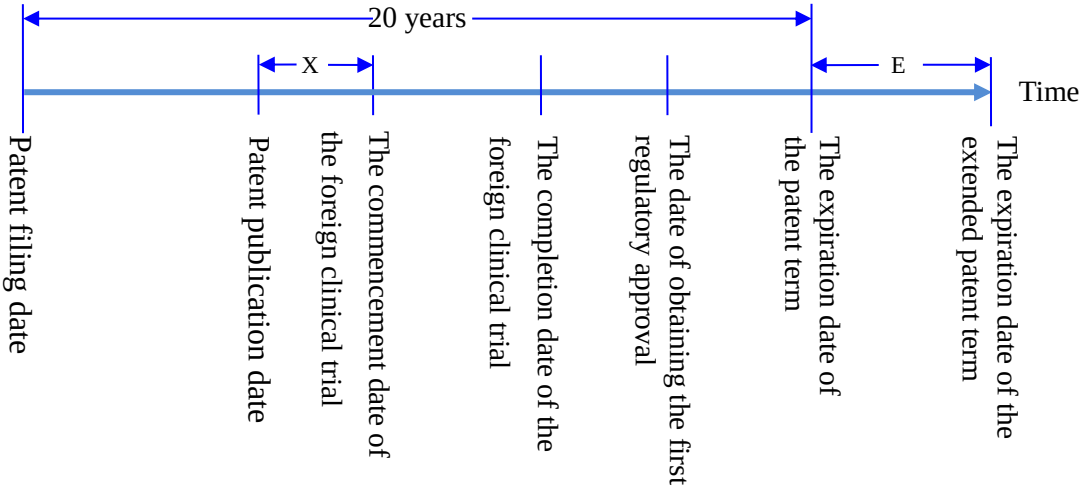



【Remarks】

Since the commencement date of foreign clinical trials is earlier than the publication date of the patent, the period (X) from the start date of the trial to the publication date of the patent is not included for the period of granting the extension term. Therefore, the period of the foreign clinical trial shall be calculated from the publication date to the completion date of the foreign clinical trial. (note: "E" is the sum of the domestic and/or foreign clinical trial period conducted to obtain a drug permit license issued from the WOWH and the examination period for domestic regulatory approval, deducting the period of inaction attributable to the applicant and the overlapping period of aforementioned periods, calculated in units of days； if E≧5, still limited to 5 years.)

**Case 2.**

The commencement date of foreign clinical trials is after the publication date of the patent, and its start date shall be counted from the commencement date of the foreign clinical trials.

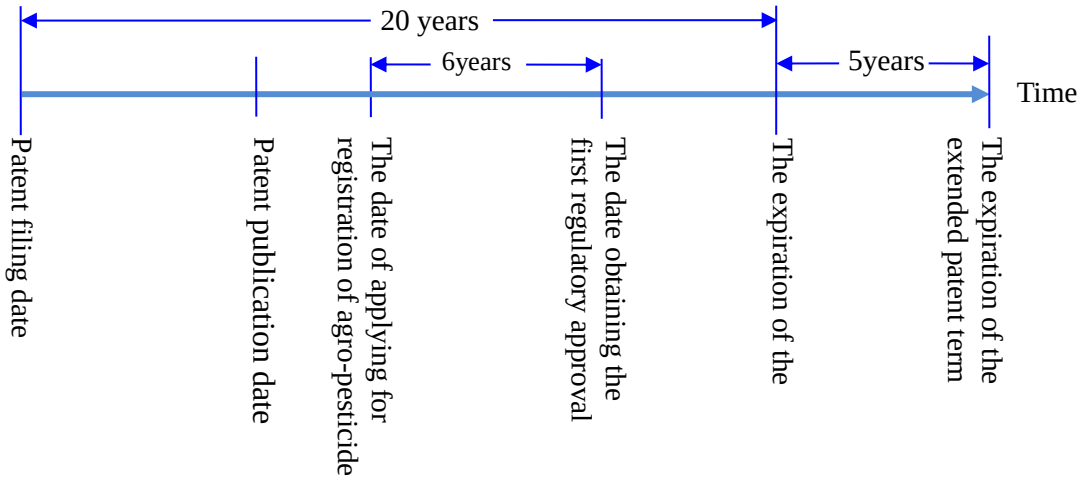



【Remarks】

Since the commencement date of foreign clinical trials is later than the patent publication date, the period (X) from the patent publication date to the commencement date of the trials cannot be calculated for granting the extension period (E).

**Case 3.**

The period from the date of applying for registration of agro-pesticide after the date of patent publication to the date of obtaining a license is over 5 years.

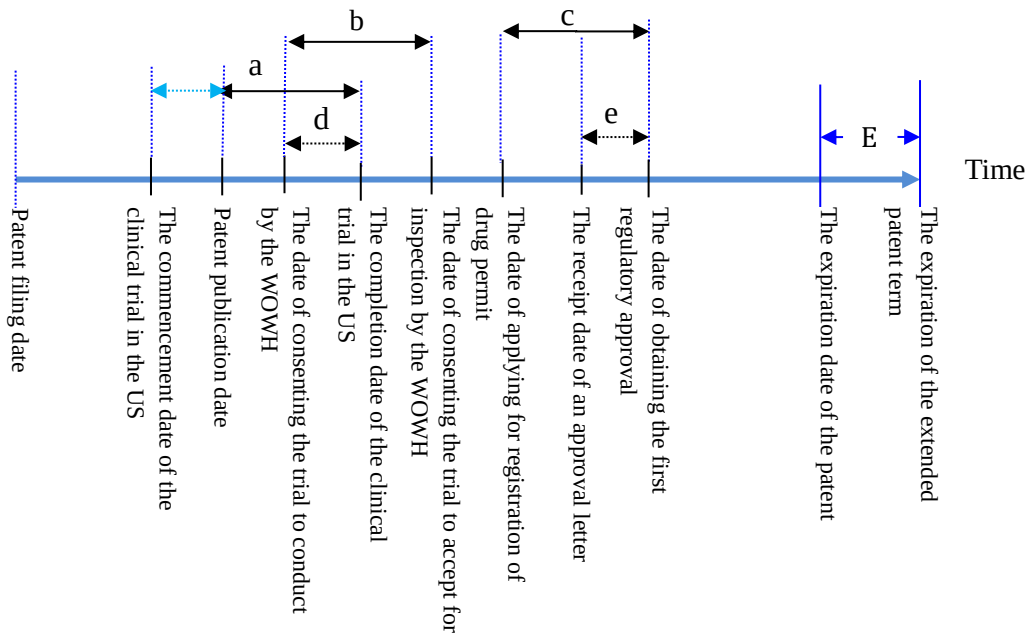



【Remarks】

Since the date of application for registration of agro-pesticide is after the patent publication date, the period required for obtaining the approval shall be calculated from the date of applying for registration of agro-pesticide to the day before the first regulatory approval is obtained. And although the period required for obtaining the approval is 6 years, it is still limited to 5 years.

**Case 4.**

The calculation of deducting the overlapping period and the period attributable to the applicant's inaction.




【Remarks】

Where the application of extension is based on the clinical trial in the United States, since the commencement date of the clinical trial in the US is before the date of patent publication, the period of the clinical trial in the US is calculated from the date of patent publication to the completion date of the clinical trial in the US (a); the period of domestic clinical trial is calculated from the date of consenting the trial to conduct by the WOWH to the date of consenting the trial to accept for inspection by the WOWH (b)；the examination period for domestic regulatory approval is calculated from the date of application for registration of drug permit to the day before the first regulatory approval is obtained (c); the period of inaction attributable to the applicant is the period from the date after the receipt date of an approval letter to the day before the date of the first regulatory approval obtained (e).

The granted extension period (E) = the period of foreign clinical trial (a) + the period of domestic clinical trial (b) + the examination period for domestic regulatory approval (c) – the overlapping period between the period of clinical trial in The US and the period of domestic clinical trial (d) - the period of inaction attributable to the applicant (e). (if E≧5, the limited is still 5 years)

## 5. Examination decision of the extension application

The Specific Patent Agency shall assign a patent examiner to examine a request for patent term extension, render a written decision and serve it to the patentee. Act 55

### 5.1 The record of a granted decision

Where the extension is granted after examination, the granted extension term shall not exceed the period during which the invention cannot be exploited in order to obtain a regulatory approval. If the time period in which the invention cannot be exploited for the purpose of obtaining a regulatory approval exceeds 5 years, the granted period is still limited to 5 years. The syllabus of the decision shall specify the granted extension time period, and if the period is less than 5 years, it shall be recorded by day unit as "the patent term is granted to extend for ○ days, and expires on dd/mm/yyyy"; and if the period exceeds 5 years, the syllabus shall be recorded as "the patent term is granted to extend for 5 years, and expires on dd/mm/yyyy". However, it should be noted, if after examination of the patent term extension request, in the event that the time period during which the invention cannot be exploited for obtaining a regulatory approval exceeds the requested extension period, the extended period to be granted shall be limited to the requested extension period. Act 53. Ⅱ Reg. 9

The approval decision of the extension application shall record the granted subject matter (substance, use or manufacturing process) of the approval extension. The writing should be based on the indications first, the active ingredients after, and the manufacturing process should add indication for its definition. Taking the pharmaceutical invention as an example, where the subject of the granted extension is "active ingredient", the writing should be "the active ingredient for treating (indication)"; where the subject of the granted extension is "use", the writing should be "the use (indication) of the (active ingredient)"; where the subject of the granted extension is "manufacturing process", the writing should be "the manufacturing process of the active ingredient used to treat (indication)". Where the subject of the granted extension covers substance, use and manufacturing process in the meantime, if the content of the indication recorded in the regulatory approval is too redundant, the indications can be described in a concise way when the indications are mentioned in the second time, for example, "the aforementioned use (indication) of the (active

ingredient); the manufacturing process of the (active ingredient) used to treat aforementioned indication", etc.

### 5.2 Effect of the decision of application of extension

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If the patent term has expired before the application of extension is granted, the patent term shall be fictitiously deemed to have been extended from the day following the expiration of the original patent right period; however, if the result of the application of extension is not granted, the fictitious effect is never occurred from the beginning, it means the patent term shall expire on the original patent expiration date.

## 6. The scope of granted invention patent term extension

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The scope of a patent, of which a term extension has been granted, shall be limited to only the effective ingredients and uses stated in the regulatory approval concerned, it shall not extend to other substances, uses or manufacturing process not stated in the regulatory approval concerned. Specifically, for the invention relating to substance, the scope of the patent during the extended patent term is limited to the effective ingredients stated in the first regulatory approval concerned and its approved use only; for invention relating to use, the scope of the patent during the extended patent term is limited to the approved use of the active ingredients stated in the first regulatory approval concerned only; for invention relating to manufacturing process, the scope of the patent during the extended patent term shall be limited to the manufacturing process of the active ingredient used for approved use stated in the regulatory approval concerned only. The claims of a patent, of which a term extension has been granted, cover substance claim, use claim and manufacturing process claim, the scope of the patent during the patent term shall be limited to the effective ingredients used for the approved use stated in the regulatory approval concerned, the approved use of the active ingredient and the manufacturing process of the active ingredient used for the approved use stated in the regulatory approval concerned.

**Example 1.**

Where a publication patent originally claims a manufacturing process of aspirin, in the event of applying for a patent term extension based on a regulatory approval of aspirin for treating migraine, the scope of the patent,

of which its term extension has been granted, shall be limited to the manufacturing process of the aspirin used for treating migraine only.

**Example 2.**

Where a publication patent originally claims an aspirin, in the event of applying for a patent term extension based on a regulatory approval of aspirin for treating migraine, the scope of the patent, of which its term extension has been granted, shall be limited to the aspirin used for treating migraine only.

**Example 3.**

Where a publication patent originally claims a use of compound A to prevent and control insect pests of dicotyledonous plants, in the event of applying for patent term extension based on a pesticide permit license, of which the active ingredient is "compound a" ("a" is covered by "A"), and the method and scope of use are suitable for killing apple (crop name) fruit flies (name of pests), the scope of the patent, of which its term extension has been granted, shall be limited to the use of "compound a" for killing "apple fruit flies" only.

**7. Transitional matters**

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In respect of an application of an invention patent term extension that has been filed prior to the amendment of this Act, if the decision has not been made and the invention patent right still exists after the amendment of this Act, the regulations of the amended Act shall be applied. The above-mentioned regulations also include stipulation in the "Regulations Governing the Determination of Patent Term Extension" and the examination guideline in the "Extension of Patent Term" of the "Substantive Examination for Invention Patent".

In respect of an application of an invention patent term extension that has been filed prior to the implementation of the amendment of this Act, if the examination begins after the amendment of this Act, the reasons for application of extension, the period, and the certificated documents to be attached, etc., according to the regulations after the implementation of the amendment of this Act, if there are reasons for incompleteness, the certificated documents cannot prove the period during which the invention cannot be exploited for the purpose of obtaining a regulatory approval, or the certificated documents are not complete, etc. In case of these circumstances,

the applicant shall be notified to apply for a reply, supplementary explanation or supplementary certificated documents , and if there is any doubt, it shall send a letter to the central competent authority in charge of the business to assist in confirmation. The applicant has been notified to apply for a reply or correction, if the applicant fails to apply for a reply or correction within the time limit, or cannot be overcome after the application for the reply or correction, it shall be render a decision in accordance with the regulations after the implementation of the amendment of this Act.

## 8. Appendix

### 8.1 Example of a list regarding the period of domestic and foreign clinical trials of pharmaceuticals

(1) A list regarding the period of domestic clinical trials (Note: that the clinical trials completed before the patent publication do not need to be filled in)

| Serial Number | Study Title | Protocol Number | The date of an official consent letter sent by the MOHW for consenting the applicant to carry out the domestic clinical trial (including the bridging study) are consented for inspection | The expiration of a domestic clinical trial for a pharmaceu-tical refers to the date of an official consent letter for inspection of reports sent by the MOHW while the reports of the domestic clinical trial | Name of test drug (including product name, active ingredient, dosage form, content) | Source of information submitted for review |
|---|---|---|---|---|---|---|
| 1 | A randomiz-ed, double-blind, placebo-controlled trial with X as an additional treatment to evaluate the | ******** | yy/mm/dd | yy/mm/dd | X | Page O of Disc O submission for Review |

| | | | | | | |
|---|---|---|---|---|---|---|
| | efficacy and safety of Y in treating patients with type II diabetes | | | | | |
| 2 | A multi-center, randomiz-ed, double-blind, placebo-controlled Phase III clinical study. To evaluate the safety and efficacy of using X and Y combin-ation therapy for patients with type II diabetes who only receive Y mono-therapy for poor blood sugar control | ******** | yy/mm/dd | yy/mm/dd | X | Page O of Book O submission for Review |

(2) A list regarding the period of foreign clinical trials (Note: that the clinical trials completed before the patent publication do not need to be filled in)

| Serial Number | Study Title | Protocol Number | Start date of Clinical trial | Completion date of Clinical trial | Name of Test Drug (including product name, active ingredient, dosage form, content) | Source of Information submitted for review |
|---|---|---|---|---|---|---|
| 1 | Long-term trial to assess the effective-ness and safety of X patch in early stage parkin-son's disease | ******** | yy/mm/dd | yy/mm/dd | X | Page O of Disc O submission for Review. |

## 8.2 Example of a list regarding the period of domestic and foreign field tests for a pesticide

| Serial Number | Plan Name of Field test | Plan number of Field test | Start date of Field test | Completion date of Field test |
|---|---|---|---|---|
| 1 | 39.5%SC Fujecamide used for Citrus anthracnose | 99EX****-10 | yy/mm/dd | yy/mm/dd |
| 2 | 39.5%SC Fujecamide used for Citrus anthracnose | 99EX****-11 | yy/mm/dd | yy/mm/dd |
| 3 | 39.5%SC Fujecamide used for Citrus anthracnose | 99EX****-12 | yy/mm/dd | yy/mm/dd |

(Note: that the field tests completed before the patent publication do not need to be filled in)